

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1434]

Guidance for Industry on Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System." The guidance provides recommendations to sponsors of investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplements to these applications who wish to request a waiver of in vivo bioavailability (BA) and bioequivalence (BE) studies for immediate-release solid oral dosage forms.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

DMB

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Certifier	Jan W. Winkler

FOR FURTHER INFORMATION CONTACT: Mei-Ling Chen, Center for Drug Evaluation and Research (HFD-350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5688.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System." This guidance provides recommendations on when in vivo BA/BE studies may be waived for IND's, NDA's, and ANDA's during either the pre- or postapproval period.


Although in vivo documentation of BA and BE has been required for many drug products, in some cases FDA has allowed the use of in vitro methods for documenting BA and BE. As noted both at 21 CFR 320.22, "Criteria for Waiver of Evidence of In Vivo Bioavailability or Bioequivalence," and at 21 CFR 320.24, "Types of Evidence to Establish Bioavailability or Bioequivalence," many options exist to allow demonstration of BA and BE through in vitro methods. This guidance describes recommendations for requesting waivers of in vivo BA/BE studies on the basis of the solubility and intestinal permeability of the drug substance and dissolution characteristics of the drug product, based on a biopharmaceutics classification system.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on the waiver of in vivo BA and BE studies for immediate-release solid oral dosage forms based on a biopharmaceutics classification system. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

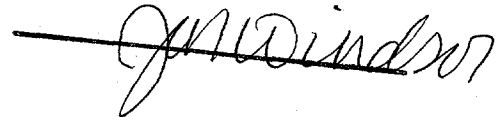
found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/18/00
August 18, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy:

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